

§ 1304.22

21 CFR Ch. II (4–1–96 Edition)

controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

[36 FR 7792, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.22 Records for manufacturers.

Each person registered or authorized (by § 1301.22(b) or § 1307.15 of this chapter) to manufacture controlled substances shall maintain records with the following information:

(a) For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form,

(1) The name of the substance;

(2) The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

(3) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

(4) The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him, including the date, quantity, and import permit or declaration number for each importation;

(5) The quantity used to manufacture the same substance in finished form, including:

(i) The date and batch or other identifying number of each manufacture;

(ii) The quantity used in the manufacture;

(iii) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter);

(iv) The number of units of finished form manufactured;

(v) The quantity used in quality control;

(vi) The quantity lost during manufacturing and the causes therefor, if known;

(vii) The total quantity of the substance contained in the finished form;

(viii) The theoretical and actual yields; and

(ix) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(6) The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in paragraph (a)(5) of this section;

(7) The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;

(8) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation;

(9) The quantity distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed;

(10) The originals of all written certifications of available procurement quotas submitted by other persons (as required by § 1303.12(f) of this chapter) relating to each order requiring the distribution of a basic class of controlled substance listed in Schedule I or II.

(b) For each controlled substance in finished form,

(1) The name of the substance;

(2) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(3) The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to paragraph (a)(5) of this section;

(4) The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address, and registration number of the person from whom the units were received;

(5) The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;

(6) The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

(i) The date and batch or other identifying number of each manufacture;

(ii) The operation performed (e.g., repackaging or relabeling);

(iii) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes for such losses, if known; and

(iv) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(7) The number of commercial containers distributed to other persons, including the date of and number of containers in each distribution, and the name, address, and registration number of the person to whom the containers were distributed;

(8) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(9) The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed,

and the quantity in finished form distributed or disposed.

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EDITORIAL NOTE: For FR citations affecting § 1304.22, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 1304.23 Records for distributors.

Each person registered or authorized (by § 1301.22(b) or §§ 1307.11–1307.14 of this chapter) to distribute controlled substances shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(c) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received;

(d) The number of commercial containers or each such finished form imported directly by the person (under a registration or authorization to import), including the date of, the number of commercial containers in, and the import permit or declaration number for, each importation;

(e) The number of commercial containers of each such finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address, and registration number of the person to whom the containers were distributed;

(f) The number of commercial containers of each such finished form exported directly by the person (under a registration or authorization to export), including the date of, the number of commercial containers in, and the export permit or declaration number for, each exportation; and